

to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

PCT Rule 13.2 requires that the inventions of a group share “special technical features” that define a contribution to the art in order to satisfy unity of invention. The Examiner alleges that the compounds involved in the claimed invention justify a restriction requirement because they do not share a significant structural element. The Examiner further alleges that the “vastness of the claimed subject matter and the complications in understanding the claimed subject matter” impose an undue search burden.

However, the applicants point out that the PCT Administrative Instructions indicate that unity of invention is not lacking merely because a common structural element is limited, as long as all of the compounds in the group “belong to a recognized class of chemical compounds in the art to which the invention pertains.” Annex B, Part 1(f)(i)(B)(2). The applicants believe that the classes of primary formamides (claim 1) and primary amines (claim 2) form recognized classes which “will behave in the same way in the context of the claimed invention.” Annex B, Part 1(f)(iii). Thus the compound genus should not warrant a restriction requirement.

The Applicants traverse the restriction requirement because the subject matter of the claims presented is united by a single general inventive concept, and the breadth of the compound genus involved should not alone justify restriction. Here, the special technical features include the use of a peptide deformylase enzyme with a bivalent metal cation; an enzymatic process to accomplish an enantioselective transformation of a common functional group; enantioselective interconversion of a primary amine and its corresponding formamide; and a process for preparing a mixture that contains a primary amine and its corresponding N-formyl compound (a primary formamide), both of which have enhanced optical purity. Furthermore, the limitation that the claimed transformation is catalyzed by an enzyme, peptide deformylase, drastically limits the alleged “vastness” of the claimed subject matter and alleviates much of the alleged burden on examination. Furthermore, the Groups created by the Examiner would not address the asserted

“complication” of understanding the subject matter, since the subject matter to be comprehended remains common to each of the Groups proposed by the Examiner.

The inventive concept uniting the claimed subject matter is the discovery by the applicants that enzymes having peptide deformylase activity are useful for interconverting primary amines and their corresponding primary formamides, that the interconversion requires a bivalent metal cation as a cofactor; and that the enzymatic interconversion is enantioselective (i.e., it results in enhanced optical purity). The enzymatic reaction can begin with either a primary amine or a primary formamide: it runs in either direction, depending on the presence of a formylating agent and a bivalent metal cation. The reaction can thus be used to simultaneously prepare enantiomerically enriched samples of both the primary amine and its corresponding primary formamide, using either compound as the starting material for the reaction.

Claim 1 describes the enzymatic process when starting with a primary formamide. The process is scarcely dependent on the nature of the R1, R2 and Y substituents: it operates on a wide array of primary formamides, as the claim suggests. The dependent claims 4-11 describe the conditions of the process more precisely without narrowing the compound genus to which the reaction can apply. The applicants are thus confused by the Examiner’s definition of this group (and each of the other groups, as well) as excluding compounds containing heterocyclic or heteroaryl groups, since the nature of the R1, R2 and Y groups is not central to the inventive concept. The inventive concept resides in the use of an enzyme to enantioselectively transform one functional group into another, thus enhancing optical activity, rather than in the nature of the compound to be transformed. Thus the applicants assert that the Examiner’s focus on the chemical structure of a single embodiment of the invention is misplaced in assessing unity of invention.

Claims 6-11 were grouped by the Examiner with claim 1 (in part) as Group I; but it is unclear why these dependent claims were included while claims 4 and 5 were grouped separately as part of Group II. The applicants view claims 4, 5, and 6 as more precisely defining the peptide deformylase enzyme of claim 1: each defines a subgenus of the genus of peptide deformylase enzymes covered by claim 1, so the reason for separating claim 6 from claims 4 and 5 is unclear.

Claims 4-6 define peptide deformylases of interest in different ways, but they do not differ in inventive concept. Claims 7-11 define the reaction conditions for the transformation more precisely, but it is not clear why these would be considered a separate inventive concept, either: they are not 'variants' of the process claimed in claim 1, they each define a subset of suitable conditions for the process of claim 1. Furthermore, while electing group I, the applicants note that the species elected for searching falls in both Groups I and II as defined by the Examiner. Thus the applicants believe that Groups I and II should not be separated: they represent a single general inventive concept.

It is similarly unclear why Groups III and IV were separated by the Examiner. Here again, the Examiner proposes two groups, both using the same compound genus, that of claim 2 but excluding compounds containing heterocycles or heteroaryl groups. Then the Examiner distinguishes the Groups based on the dependent claims to be included. Group III includes dependent claims 14-19, while Group IV includes dependent claims 12-13. Here again, the Examiner groups two dependent claims (12 and 13) further describing the peptide deformylase enzyme to be used for the process of claim 2 into one group (Group IV), while the other such dependent claim (claim 14) is grouped with the dependent claims describing the process conditions more precisely (15-19). The applicants assert that Groups III and IV share the same general inventive concept, though: both use peptide deformylase to enzymatically convert a primary amine into a mixture of two compounds, a primary formamide and its primary amine, where each of the two compounds has enhanced optical purity. Thus Groups III and IV should not be separated, either.

Finally, both claims 1 and 2 describe the use of the process of this invention for preparing *a mixture of primary amine and primary formamide*, each of enhanced optical purity. Claim 1 describes the process when starting with a primary formamide; claim 2 describes using the same enzyme and bivalent metal cation to prepare a mixture of the same compounds by starting with the primary amine instead of the formamide. Thus the applicants assert that separating the claims of Groups I and II from those of Groups III and IV is also inappropriate: one pair of Groups represents running a reaction in the forward direction, while the other pair of Groups represents running the same reaction in the opposite direction. And both ways produce a mixture of a primary formamide

and its corresponding primary amine, each of which is enantiomerically enriched due to the enantioselectivity of the peptide deformylase enzyme. Thus the applicants assert that the claims represent a single general inventive concept, and that no restriction requirement should have been imposed.

Applicants thus request reconsideration of the restriction requirement in light of the above comments. Applicants also request examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246152014500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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